UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

MICHAEL PARDI, et al.,

Plaintiffs,

v.

TRICIDA, INC., et al.,

Defendants.

Case No. 21-cv-00076-HSG

ORDER GRANTING IN PART AND DENYING IN PART MOTION TO DISMISS

Re: Dkt. No. 128

This putative securities class action was filed against Defendants Tricida, Inc. and Gerrit Klaerner (collectively, "Defendants"). On June 1, 2021, Lead Plaintiff Jeffrey Fiore filed an amended complaint alleging violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder. *See* Dkt No. 72 at ¶ 2. The Court dismissed Fiore's amended complaint with leave to amend. *See Pardi v. Tricida, Inc.*, No. 21-CV-00076-HSG, 2022 WL 3018144, at *1 (N.D. Cal. July 29, 2022) ("Order"). Fiore then filed a second amended complaint reasserting the same claims. *See* Dkt. No. 142[1] ("SAC").

Pending before the Court is Klaerner's motion to dismiss the SAC, for which briefing is complete.[2] *See* Dkt. Nos. 144-1 ("Mot."), 143 ("Opp."), 144-2 ("Reply"). The Court finds the matter appropriate for disposition without oral argument and the matter is deemed submitted. *See* Civil L.R. 7-1(b). For the following reasons, the Court **GRANTS** the motion in part and **DENIES**

[1] The Court cites to redacted versions of the pleadings publicly filed on the docket pursuant to its recent sealing order. *See* Dkt. No. 141.

[2] Defendant Tricida, Inc. filed a voluntary petition for relief under Chapter 11 of the Bankruptcy Code, and Fiore voluntarily dismissed Tricida from the case in March 2023. *See* Dkt. No. 132. Accordingly, the only remaining defendant in this case is Klaerner. The Court refers to Klaerner and Tricida collectively as "Defendants" since both are alleged to have made statements challenged in the operative complaint, notwithstanding Tricida's later dismissal.

it in part.

I. BACKGROUND

A. Parties

Tricida is a clinical-stage biopharmaceutical company incorporated in Delaware with principal executive offices in South San Francisco, California. SAC at ¶¶ 40, 45. Klaerner was Tricida's Chief Executive Officer and President at the time the SAC was filed. *Id*. at ¶ 41. Fiore alleges he was damaged by Defendants' misrepresentations and omissions because he "purchased Tricida common stock at artificially inflated prices." *Id*. at ¶ 34.

B. Factual Allegations

In May 2018, Tricida completed its Phase 3 clinical trial for veverimer, a drug intended to slow the progression of chronic kidney disease ("CKD") through treatment of metabolic acidosis. SAC at ¶¶ 45, 62. In a June 5, 2018 press release, Tricida announced that the Phase 3 study for veverimer "was conducted at 47 sites in the United States and Europe," and that the study "met both its primary and secondary endpoints in a statistically significant manner." *Id.* at ¶ 62. Following the trial results, Tricida held its initial public offering ("IPO") on June 28, 2018 and began trading that same day on the Nasdaq Global Select Market. *Id*. at ¶¶ 7, 65. In late August 2019, Tricida submitted its New Drug Application ("NDA") for veverimer to the United States Food and Drug Administration ("FDA") under the FDA's Accelerated Approval Program. *Id*. at ¶ 71. The FDA accepted Tricida's NDA for review three months later. *Id*.

Beginning in May 2020, Tricida began to receive indications from the FDA that there were issues with its NDA. *See, e.g*., *id*. at ¶¶ 24–25, 176. Early that month, Tricida executives met with representatives from the FDA in which the FDA shared that it had concerns regarding: (1) "the magnitude and durability of the treatment effect on the surrogate marker of serum bicarbonate demonstrated in the TRCA-301 and TRCA-301E trials" and (2) "the applicability of data from the TRCA-301 and TRCA-301E trials to the U.S. population." *Id.* at ¶ 27.

On July 15, 2020, Tricida issued a press release stating that the FDA had notified it that the Agency "ha[d] identified deficiencies that preclude discussion of labeling and postmarketing requirements/commitments at this time." *Id.* at ¶ 28. Tricida issued another press release on

August 24, 2020 stating that it had received a Complete Response Letter from the FDA on August 21, 2020 explaining that Tricida's Phase 3 trial was inadequate on its own to demonstrate the efficacy of veverimer. *Id.* at ¶¶ 29, 177, 179. The FDA further stated that it required additional data regarding the magnitude and durability of veverimer's treatment effect and on the applicability of that effect to the U.S. population. *Id.* at ¶ 177. Two months later, on October 29, 2020, Tricida announced that the FDA had informed it that the FDA was "unlikely to rely solely on serum bicarbonate data for determination of efficacy" and would "require evidence of veverimer's effect on CKD progression from a near-term interim analysis of the VALOR-CKD trial for approval under the Accelerated Approval Program." *Id.* at ¶ 180. Finally, on February 25, 2021, Tricida announced in a press release that the FDA had denied the appeal of its application denial. *Id.* at ¶¶ 33, 185.

C. Procedural Background

In January 2021, Plaintiff Michael Pardi filed this lawsuit asserting violations of Sections 10(b) and 20(a) of the Securities Exchange Act and Rule 10b-5. *See* Dkt. No. 1 at ¶ 1. In April 2021, the Court appointed Fiore as Lead Plaintiff and Block & Leviton LLP as Lead Counsel. Dkt. No. 65. Fiore seeks to represent "a class consisting of all purchasers of the common stock of Tricida" from June 28, 2018 through February 25, 2021. SAC at ¶¶ 3, 201.

II. LEGAL STANDARD

A. Rule 12(b)(6) Standard

Federal Rule of Civil Procedure 8(a) requires that a complaint contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). A defendant may move to dismiss a complaint for failing to state a claim upon which relief can be granted under Federal Rule of Civil Procedure 12(b)(6). "Dismissal under Rule 12(b)(6) is appropriate only where the complaint lacks a cognizable legal theory or sufficient facts to support a cognizable legal theory." *Mendiondo v. Centinela Hosp. Med. Ctr.*, 521 F.3d 1097, 1104 (9th Cir. 2008). To survive a Rule 12(b)(6) motion, a plaintiff must plead "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A claim is facially plausible when a plaintiff pleads "factual content that allows the court to draw

the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

In reviewing the plausibility of a complaint, courts "accept factual allegations in the complaint as true and construe the pleadings in the light most favorable to the nonmoving party." *Manzarek v. St. Paul Fire & Marine Ins. Co.*, 519 F.3d 1025, 1031 (9th Cir. 2008). However, courts do not "accept as true allegations that are merely conclusory, unwarranted deductions of fact, or unreasonable inferences." *In re Gilead Scis. Sec. Litig.*, 536 F.3d 1049, 1055 (9th Cir. 2008).

B. Heightened Pleading Standard

Section 10(b) of the Securities Exchange Act of 1934 provides that it is unlawful "[t]o use or employ, in connection with the purchase or sale of any security registered on a national securities exchange or any security not so registered . . . any manipulative or deceptive device or contrivance . . . . " 15 U.S.C. § 78j(b). Under this section, the SEC promulgated Rule 10b–5, which makes it unlawful, among other things, "[t]o make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading." 17 C.F.R. § 240.10b–5(b). To prevail on a claim for violations of either Section 10(b) or Rule 10b–5, a plaintiff must prove six elements: "(1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation." *Stoneridge Inv. Partners, LLC v. Scientific–Atlanta, Inc.*, 552 U.S. 148, 157 (2008).

At the pleading stage, a complaint alleging claims under Section 10(b) and Rule 10b–5 must not only meet the requirements of Federal Rule of Civil Procedure 8, but also satisfy the heightened pleading requirements of both Federal Rule of Civil Procedure 9(b) and the Private Securities Litigation Reform Act ("PSLRA"). *In re Rigel Pharm., Inc. Sec. Litig.*, 697 F.3d 869, 876 (9th Cir. 2012). Under Rule 9(b), claims alleging fraud are subject to a heightened pleading requirement, which requires that a party "state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). Additionally, all private securities fraud complaints are

subject to the "more exacting pleading requirements" of the PSLRA, which require that the complaint plead with particularity both falsity and scienter. *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 990 (9th Cir. 2009).

III. REQUEST FOR JUDICIAL NOTICE

Klaerner asks the Court to take judicial notice of 30 exhibits. *See* Dkt. No. 129 (request for judicial notice of 28 exhibits); Dkt. No. 136 (supplemental request for judicial notice of 2 exhibits). He argues that the exhibits are appropriately subject to the Court's consideration under the doctrines of judicial notice and incorporation by reference. Fiore filed no objection to either of Klaerner's requests for judicial notice.

A. Legal Standard

"Generally, district courts may not consider material outside the pleadings when assessing the sufficiency of a complaint under Rule 12(b)(6) of the Federal Rules of Civil Procedure." *In re Eventbrite, Inc. Sec. Litig.*, No. 18-CV-02019-EJD, 2020 WL 2042078, at *7 (N.D. Cal. Apr. 28, 2020) (citing *Lee v. City of Los Angeles*, 250 F.3d 668, 688 (9th Cir. 2001); *Khoja v. Orexigen Therapeutics, Inc.*, 899 F.3d 988, 998 (9th Cir. 2018)); *see also* Fed. R. Civ. P. 12(d). "This rule does not apply to the incorporation by reference doctrine or judicial notice under Federal Rule of Evidence 201." *Eventbrite*, 2020 WL 2042078, at *7 (citing *Khoja*, 899 F.3d at 998).

A court may take judicial notice of an "adjudicative fact" pursuant to the Federal Rules of Evidence, if that fact is one "that is not subject to reasonable dispute because it: (1) is generally known within the trial court's territorial jurisdiction; or (2) can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b). Thus, under Rule 201, courts may "take judicial notice of matters of public record, but not of facts that may be subject to reasonable dispute." *United States v. Corinthian Colls.*, 655 F.3d 984, 999 (9th Cir. 2011) (internal quotation marks and citation omitted).

In the Ninth Circuit, incorporation by reference is a doctrine that "treats certain documents as though they are part of the complaint itself." *Khoja*, 899 F.3d at 1002. A document may be incorporated by reference into a complaint "if the plaintiff refers extensively to the document or the document forms the basis of the plaintiff's claim." *United States v. Ritchie*, 342 F.3d 903, 908

(9th Cir. 2003). "Once a document is deemed incorporated by reference, the entire document is assumed to be true for purposes of a motion to dismiss, and both parties—and the Court—are free to refer to any of its contents." *In re NVIDIA Corp. Sec. Litig.*, 768 F.3d 1046, 1058 n.10 (9th Cir. 2014) (internal quotation marks and citation omitted).

B. Analysis

Exhibits 1-7 are public documents filed with the SEC. Exhibit 17 is a public decisional memo from the Office of Drug Evaluation, which Klaerner offers to provide publicly available information about a previous drug development program he led. Exhibit 22 is an FDA Advisory Committee Calendar document publicly posted by the FDA. Exhibits 23–26 are documents publicly posted by the National Institutes of Health. The Court previously granted judicial notice as to Exhibits 1–6 and 22–26 without taking notice of the truth of any of the facts asserted. *See* Order at *3. The "accuracy" of all these public documents "is not reasonably subject to dispute." *Wochos v. Tesla, Inc.*, No. 17-CV-05828-CRB, 2018 WL 4076437, at *1 (N.D. Cal. Aug. 27, 2018); *see Dreiling v. Am. Exp. Co.*, 458 F.3d 942, 946 n.2 (9th Cir. 2006) (noting that SEC filings are subject to judicial notice); *In re Yahoo! Inc. Customer Data Sec. Breach Litig.*, No. 16-MD-02752-LHK, 2017 WL 3727318, at *10 (N.D. Cal. Aug. 30, 2017) ("[B]oth SEC filings and documents on government websites are proper subjects of judicial notice."). Accordingly, the Court **GRANTS** Klaerner's request for judicial notice as to Exhibits 1–7, 17, and 22–26 for the purpose of considering what was disclosed to the market. In doing so, the Court does not assume the truth of any of the facts asserted. *Wochos*, 2018 WL 4076437, at *2.

Exhibits 8–14 and 28 and Reply Exhibit 2 are communications between Tricida and the FDA, including meeting agendas, meeting minutes, letters, Type A meeting requests, and Type C written responses. All of these exhibits except for Exhibit 13 are cited in the SAC and serve as the basis for Fiore's new allegations of falsity and scienter. Exhibits 15–16 are transcripts of earnings calls cited in the SAC, which the Court found to be properly subject to judicial notice in its prior order. *See* Order at *4. Reply Exhibit 1 is a transcript from an earnings call that is not cited in the SAC. Exhibits 8–12, 14–16, and 28, as well as Reply Exhibit 2, are incorporated by reference because the SAC explicitly and repeatedly refers to excerpts of these exhibits to support its claims.

See Khoja, 899 F.3d at 998 ("a defendant may seek to incorporate a document into the complaint 'if the plaintiff refers extensively to the document or the document forms the basis of the plaintiff's claim.'") (quoting *Ritchie*, 342 F.3d at 907); *see, e.g.*, *Mulquin v. Nektar Therapeutics*, 510 F. Supp. 3d 854, 863 (N.D. Cal. 2020) ("The Court will consider the investor presentation transcripts and investor presentation slide decks that Plaintiffs allege contain false and/or misleading statements for the purpose of determining what was disclosed to the market."). Finding these documents incorporated by reference, the Court **GRANTS** the motion as to Exhibits 8–12, 14–16, and 28 and Reply Exhibit 2. Because Exhibit 13 and Reply Exhibit 1 are not specifically referenced in the complaint or relevant to the Court's analysis because they are offered to dispute the SAC's well-pled allegations, Klaerner's requests as to those exhibits is **DENIED**. *See In re Lyft Inc. Sec. Litig.*, 484 F. Supp. 3d 758, 764 (N.D. Cal. 2020) (denying request for judicial notice where exhibits were neither specifically referenced in the operative complaint nor relevant to the Court's analysis).

Exhibits 18–21 are four publications from the scientific journal, *The Lancet*. The Court previously took judicial notice of these publications to indicate what was in the public realm at the time. *See* Order at *4 (citing cases). For the same reasons, the Court **GRANTS** Klaerner's request for judicial notice as to Exhibits 18–21, again without taking notice of the truth of the facts asserted. Finally, Klaerner seeks judicial notice of Exhibit 27, which is a public court filing related to Tricida's bankruptcy proceedings. The Court "may take judicial notice of court filings and other matters of public record," *Reyn's Pasta Bella, LLC v. Visa USA, Inc.*, 442 F.3d 741, 746 n.6 (9th Cir. 2006), and in light of Fiore's lack of opposition, the Court **GRANTS** Klaerner's request as to Exhibit 27.

IV. MOTION TO DISMISS

Fiore alleges that Klaerner[3] violated Section 10(b) of the Exchange Act and Rule 10b-5 by making false or misleading statements either intentionally or recklessly, starting with the June 28, 2018 Registration Statement and Prospectus accompanying Tricida's IPO and ending with

[3] In light of Tricida's dismissal from this action, the Court only assesses whether Fiore's allegations as to statements attributable to Klaerner plausibly state a claim for securities fraud.

Tricida's February 25, 2021 press release. *See, e.g.*, SAC at ¶¶ 7, 33, 65, 185, 188. Klaerner moves to dismiss on two grounds: (1) the challenged statements were not materially false or misleading; and (2) Fiore fails to adequately plead facts giving rise to a strong inference of scienter. *See* Mot. at 6–7.[4]

To plead a claim under section 10(b) and Rule 10b-5, Fiore must allege: "(1) a material misrepresentation or omission by [Klaerner]; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation." *Macomb Cty. Emps. Ret. Sys. v. Align Tech., Inc.*, 39 F.4th 1092, 1098 (9th Cir. 2022).

As a preliminary matter, without seeking leave, Klaerner attempts to revisit statements that the Court already found sufficiently pled. *See, e.g.*, Mot. at 6 (asserting that the new FDA documents "doom[] [Fiore's] attack on all the challenged statements, including the one statement that survived the prior motion to dismiss."); *id*. at 27 ("But information before the Court for the first time now undermines [Fiore's] allegation, and the Court may appropriately revisit the issue in light of that information."); *see generally id*. at 11–18, 27–28. This is an impermissible de facto motion for reconsideration of the Court's previous order, which Klaerner neither acknowledges nor properly briefs. The Court finds that there is no basis to revisit any of its prior rulings, including the statements discussing outstanding review issues with the FDA that the Court previously found to be sufficiently pled. *See* Order at *12–14, 17–18. Accordingly, the Court only addresses the statements that it previously found inadequately pled, along with the new purported misrepresentations and allegations of scienter raised in the operative complaint.[5]

A. Material Misrepresentations or Omissions

a. Legal Standard for Falsity

Klaerner challenges Fiore's claims that his statements concerning Tricida's Phase 3

[4] All references to page numbers in filings are to the ECF pagination at the top of the document.
[5] Even if considered, the Court disagrees that anything in the new FDA documents "dooms" the SAC when "accept[ing] factual allegations in the [SAC] as true and constru[ing] the pleadings in the light most favorable to [Fiore]," *Manzarek*, 519 F.3d at 1031, as the Court must at this stage of the proceedings.

clinical trial for veverimer were false or misleading. *See* Mot. at 11–22. "Falsity is alleged when a plaintiff points to [the] defendant's statements that directly contradict what the defendant knew at that time." *Khoja*, 899 F.3d at 1008. "In setting forth the reasons why they contend that each challenged statement is misleading, securities plaintiffs may rely either on an affirmative misrepresentation theory or an omission theory." *Wochos v. Tesla, Inc.*, 985 F.3d 1180, 1188 (9th Cir. 2021) (citing 17 C.F.R. § 240.10b–5(b)). "Under Rule 10b–5, an affirmative misrepresentation is an 'untrue statement of a material fact,' and a fraudulent omission is a failure to 'state a material fact necessary in order to make the statements made, in light of the circumstances under which they are made, not misleading.'" *Id.*

"A statement is misleading if it would give a reasonable investor the impression of a state of affairs that differs in a material way from the one that actually exists." *Retail Wholesale & Dep't Store Union Local 338 Ret. Fund v. Hewlett-Packard Co.*, 845 F.3d 1268, 1275 (9th Cir. 2017) (quotations and alterations omitted). "To be misleading, a statement must be 'capable of objective verification.'" *Id.* (quoting *Or. Pub. Emps. Ret. Fund v. Apollo Grp. Inc.*, 774 F.3d 598, 606 (9th Cir. 2014)). "For example, 'puffing'—expressing an opinion rather than a knowingly false statement of fact—is not misleading." *Id.*; *see also In re Cornerstone Propane Partners, L.P.*, 355 F. Supp. 2d 1069, 1087 (N.D. Cal. 2005) ("Generally, such statements consist of forward-looking or generalized statements of optimism that are 'not capable of objective verification,' and 'lack[ ] a standard against which a reasonable investor could expect them to be pegged.'") (citations omitted). However, even "general statements of optimism, when taken in context," may be misleading "when those statements address specific aspects of a company's operation that the speaker knows to be performing poorly." *In re Quality Sys., Inc. Sec. Litig.*, 865 F.3d 1130, 1143 (9th Cir. 2017).

"Even if a statement is not false, it may be misleading if it omits material information." *Khoja*, 899 F.3d at 1008–09. "An omission is material when there is a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the total mix of information available." *Irving Firemen's Relief & Ret. Fund v. Uber Tech.*, 398 F. Supp. 3d 549, 556 (N.D. Cal. 2019) (citation omitted).

"Omissions are actionable only where they make the actual statements misleading; it is not sufficient that an investor merely would consider the omitted information significant." *Id.* (internal quotation marks and citation omitted). "For the purposes of a 10b–5 claim, a misrepresentation or omission is material if there is a substantial likelihood that a reasonable investor would have acted differently if the misrepresentation had not been made or the truth had been disclosed." *Livid Holdings Ltd. v. Salomon Smith Barney, Inc.*, 416 F.3d 940, 946 (9th Cir. 2005).

b. The Statements at Issue

1. Opinion Statements

In the SAC, Fiore challenges a number of statements made by Klaerner which were allegedly misleading as to the likelihood that Tricida would achieve accelerated approval because those representations omitted concerns raised by the FDA in its ongoing dialogue with Tricida throughout the review and approval process. For example, Klaerner stated that the TRCA-301 trial "met both its primary and secondary endpoints in a highly statistically significant manner" and that TRCA-301E "met its primary and all secondary endpoints." *See, e.g.*, SAC at ¶¶ 106, 114, 121, 123, 125, 136, 144, 155–56. Klaerner also expressed optimism about the submission, review, and approval of the NDA. *See, e.g.*, *id.* at ¶ 104 ("Based on feedback from the FDA, we believe that the data from the TRCA-101, TRCA-301 and TRCA-301E trials will provide sufficient evidence of clinical safety and efficacy to support the submission and review of an NDA for TRC101 pursuant to the Accelerated Approval Program."); *id.* at ¶ 114 (Klaerner reported on an earnings call that the combined results of the TRCA-301/TRCA-301E trial "far exceeded our expectations," and "we feel good about what we've learned in the 301E study regarding safety and efficacy, increasing our confidence for a successful VALOR-CKD trial."); *id.* at ¶ 131 ("And when you fast-forward in all the work that we've done, from a discovery to an early development, to a late stage development, agreeing with FDA, an accelerated approval path, you -- all you expect to do is to show a surrogate effect, and then you have a post-marketing commitment that ultimately then, you confirm that, that surrogate is going to translate.") (emphasis omitted); *id.* at ¶ 157 ("We believe that the data from the TRCA-101, TRCA-301 and TRCA-301E clinical trials

will provide sufficient clinical evidence of safety and efficacy to support the approval of our NDA for veverimer pursuant to the Accelerated Approval Program."). And on May 7, 2020, Klaerner stated that "[o]verall, while the FDA continues its review, we remain confident that our submission meets the standard for approval through the Accelerated Approval Program." *Id*. at ¶ 158.

Fiore contends that the representations regarding the trial's endpoints were false and misleading because Klaerner failed to disclose that the FDA had repeatedly indicated its disagreement that TRCA-301's endpoint was substantial enough to demonstrate the trial's clinical effectiveness, and the Agency had warned Defendants that simply "winning" on the primary endpoint was insufficient for accelerated approval. *Id*. at ¶¶ 122–23, 126, 137, 156. Fiore also claims that the optimistic statements about the NDA were false and misleading because they failed to disclose significant issues and feedback communicated by the FDA. *Id*. at ¶¶ 104–105, 157; *see, e.g., id*. at ¶ 115 (the FDA had "repeatedly told Defendants that it did not agree that TRCA-301/301E's endpoint was substantial enough to demonstrate clinical efficacy."). Finally, Fiore argues that the May 7, 2020 statement was false or misleading because the FDA had told Klaerner at two prior meetings that "the trial results were likely inapplicable to the U.S. population because TRCA-301/301E relied on foreign data primarily from a single site in Bulgaria and because the size of the treatment effect was too small to be 'reasonably likely' to predict clinical benefit," and that study participants largely appeared to be suffering from a different condition, Balkan Endemic Nephropathy ("BEN"), not CKD. *Id*. at ¶¶ 160–61.

The Court finds that the statements identified by Fiore are opinions, "since they inherently reflect the speaker's assessment of and judgment about the underlying circumstances." *Markette v. XOMA Corp.*, No. 15-CV-03425-HSG, 2017 WL 4310759, at *4 (N.D. Cal. Sept. 28, 2017). "Interpretations of clinical trial data are considered opinions," which "are only actionable under the securities laws if they are not honestly believed and lacked a reasonable basis." *City of Edinburgh Council v. Pfizer, Inc*., 754 F.3d 159, 170 (3d Cir. 2014). In pleading the falsity of opinion statements such as these, Fiore "must allege both that 'the speaker did not hold the belief she professed' and that the belief is objectively untrue." *City of Dearborn Heights Act 345 Police*

& Fire Ret. Sys. v. Align Tech., Inc., 856 F.3d 605, 616 (9th Cir. 2017). As the Supreme Court explained in *Omnicare*, "a statement of opinion is not misleading just because external facts show the opinion to be incorrect." *Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund*, 575 U.S. 175, 186 (2015). "[W]hether an omission makes an expression of opinion misleading always depends on context." *Id*. at 190. Investors take into account "the customs and practices of the relevant industry," "[s]o an omission that renders misleading a statement of opinion when viewed in a vacuum may not do so once that statement is considered, as appropriate, in a broader frame." *Id*.

While "general statements of optimism" made against a clearly pessimistic backdrop "may form a basis for a securities fraud claim," the SAC does not sufficiently plead an actionable claim on this basis. *Macomb*, 39 F.4th at 1099 (quoting *Police Ret. Sys. of St. Louis v. Intuitive Surgical, Inc.*, 759 F.3d 1051, 1060 (9th Cir. 2014)). Fiore fails to plausibly allege that Klaerner did not hold the optimistic beliefs he professed, or that these beliefs are objectively untrue. For example, the FDA's expression of its view that the results likely would not be applicable to the U.S. population does not show that Klaerner's confidence in the likelihood of approval was necessarily objectively false or not honestly held. *See Markette*, 2017 WL 4310759, at *5 (quoting *Dearborn Heights*, 856 F.3d at 616); *see also Omnicare*, 575 U.S. at 186 (characterizing the inquiry as focused on whether the speaker's opinion was "honestly held"). Thus, Fiore fails to plausibly plead any basis for concluding that Klaerner's opinion statements characterizing the trial results and expressing optimism about FDA approval directly contradicted what he knew at the time and were therefore false. *Khoja*, 899 F.3d at 1008.

Moreover, the Court agrees with Klaerner that there is no general requirement under the securities laws for a company to engage in a rolling, communication-by-communication disclosure of every detail arising from the back-and-forth dialogue with the FDA throughout its complex review and approval process, or to adopt the FDA's position as correct and share it with the public when discussing its product. *See* Mot. at 19–22; *see also Brody v. Transitional Hosps. Corp.*, 280 F.3d 997, 1006 (9th Cir. 2002) (rejecting argument that there is a "freestanding completeness requirement" under the securities laws). The overarching flaw with Fiore's argument is his

assumption that because the FDA communicated its views to Klaerner throughout the course of the extensive review and approval process, it follows that his statements failing to contemporaneously convey the FDA's views and accept them as true were materially misleading. But that theory does not plausibly plead falsity. Fiore does not cite, and the Court has not found, controlling Ninth Circuit authority suggesting that a company's failure to disclose the FDA's positions in real time establishes falsity under the PSLRA. To the contrary, the FDA approval process necessarily involves a dialogue between companies like Tricida and the Agency, and the company has "no legal obligation to loop the public into each detail of every communication with the FDA." *In re Dynavax Sec. Litig.*, No. 4:16-CV-06690-YGR, 2018 WL 2554472, at *7 (N.D. Cal. June 4, 2018) (quoting *Corban v. Sarepta Therapeutics, Inc.*, 868 F.3d 31, 40 (1st Cir. 2017)).

Post-*Omnicare*, other courts of appeal have rejected theories imposing such a disclosure requirement in securities fraud cases involving the FDA approval process. For example, in *Tongue v. Sanofi*, the plaintiffs "[were] sophisticated investors, no doubt aware that projections provided by issuers are synthesized from a wide variety of information, and that some underlying facts may be in tension with the ultimate projection set forth by the issuer." 816 F.3d 199, 211 (2d Cir. 2016). The Second Circuit explained that these investors, "well accustomed to the 'customs and practices of the relevant industry,'" would fully expect that the defendants and the FDA were engaged in a continuous dialogue "about the sufficiency of various aspects of the clinical trials and that inherent in the nature of [such] a dialogue are differing views." *Id.* Thus, the Second Circuit concluded the defendants' statements about the effectiveness of their drug "[could not] be misleading merely because the FDA disagreed with the conclusion—so long as Defendants conducted a 'meaningful' inquiry and in fact held that view, the statements did not mislead in a manner that [was] actionable." *Id.* at 214.

Similarly, in *In re Amarin Corp. PLC Sec. Litig.*, the Third Circuit concluded that the plaintiffs failed to plead falsity because the company's announcement of the topline results of its Phase 3 trial "did not lack a reasonable basis." No. 21-2071, 2022 WL 2128560, at *3 (3d Cir. June 14, 2022). The court also found the plaintiffs' theory of omission liability unpersuasive given that the company's contemporaneous disclosures warned of the exact risk that the plaintiffs

argued was improperly omitted. *Id*. And the court rejected the theory that the company had a duty to disclose additional information when announcing its topline results because the company had put information about the trial's placebo arm "in play." *Id*. The court recognized that "[t]here is no affirmative duty to disclose all material information, but such a duty may arise when a company chooses 'to speak about a material subject to investors.'" *Id*. (citations omitted). The Third Circuit explained, however, that while the disclosures at issue described the trial results with reference to the placebo group, "they did not make any affirmative characterizations regarding the effectiveness" of the placebo. *Id*. (citation omitted). Accordingly, "[the company's] disclosure of the topline results did not put into play either the full trial data or additional information" regarding the placebo. *Id*.

Here, as in *Amarin*, the SAC details several instances in which Klaerner *did* disclose information that Fiore argues was improperly omitted. *See* Mot. at 20–21. For example, in both the 2018 Prospectus and the Prospectus accompanying the April 2019 offering, Tricida disclosed that its application relied on "an unvalidated surrogate endpoint," and explained that "the FDA may not agree that we have achieved the primary endpoint in our pivotal Phase 3 clinical trial, TRCA-301, to the magnitude or to the degree of statistical significance required by the FDA." SAC at ¶ 108 (emphasis omitted).

Fiore claims that these disclosures were "too generalized" to actually disclaim the specific risks identified by the FDA. *See, e.g.*, SAC at ¶¶ 103, 108. The Court disagrees. "Reasonable investors understand that dialogue with the FDA is an integral part of the drug approval process, and no sophisticated investor familiar with standard FDA practice would expect that every view [] taken by Defendants was shared by the FDA." *Sanofi*, 816 F.3d at 214. Fiore does not plausibly plead that the statements at issue here "lack[ed] a reasonable basis," *Amarin*, 2022 WL 2128560, at *3, or that Defendants failed to conduct a "meaningful" inquiry and did not in fact hold the views expressed in their statements, *Sanofi*, 816 F.3d at 214. "In the absence of plausible allegations showing a conflict between Defendants' statements and the FDA feedback," *Sanofi*, 816 F.3d at 214, the SAC fails to sufficiently plead that omitting information regarding the identified topics "affirmatively led [investors like Fiore] in a wrong direction (rather than merely

omitted to discuss certain matters)." *In re OmniVision Tech., Inc. Sec. Litig.*, 937 F. Supp. 2d 1090, 1101 (N.D. Cal. 2013) (emphasis omitted); *see also Markette*, 2017 WL 4310759, at *7. And as in *Sanofi*, "fatal to [Fiore's] case is the absence of any serious conflict between the FDA's interim, albeit repeated, concerns about [the adequacy of the Phase 3 trial] and Defendants' optimism about FDA approval." *Sanofi*, 816 F.3d at 212. Ultimately, the fact that Tricida had a years-long iterative dialogue with the FDA, during which the agency unsurprisingly raised issues as to which there were differences of opinion, does not plausibly allege that the opinion statements by Klaerner identified in the SAC were false or misleading by omission under the demanding standard set by the PSLRA and cases interpreting it.

Nor does the Ninth Circuit's decision in *Schueneman* support a different result. While that case formally addressed scienter rather than falsity, the *Schueneman* court found that the plaintiff adequately pled scienter where the company reported "favorable results on everything" in animal studies and conveyed optimism about FDA approval while allegedly concealing strong indications that the drug caused cancer in rats. *Schueneman v. Arena Pharm., Inc.*, 840 F.3d 698, 702, 708 (9th Cir. 2016) (emphasis omitted). The company "did more than just express its confidence in [the drug's] future"—it affirmatively represented that "all the animal studies that [had] been completed" supported the company's case for approval. *Id.* at 708. At the time these statements were made, the company "knew the animal studies were *the* sticking point with the FDA." *Id.* (emphasis in original). The Ninth Circuit reasoned that these statements were representations about the drug that the company could not support at the time they were made. As the court explained,

> [the company] was free to express confidence in FDA approval. It might have represented that [the company] was working through some requests from the FDA and was confident the data would vindicate [the drug]. But what it could not do was express confidence by claiming that all of the data was running in [the drug's] favor. It was not.

Id.; *see also Corban*, 868 F.3d at 40 ("That the defendants neglected to mention specific factors (many of them intricate and technical) contributing to the FDA's position, while nonetheless faithfully representing that position (indeed quoting directly from FDA sources at times), strikes us as more consistent with negligence than reckless or intentional concealment.").

Along these lines, Fiore relies on a recent opinion from this district in contending that Klaerner's omissions about the FDA's concerns were actionable. Opp. at 20 (citing *Homyk v. ChemoCentryx, Inc.*, No. 21-CV-03343-JST, 2023 WL 3579440, at *8 (N.D. Cal. Feb. 23, 2023)). In *Homyk*, the plaintiff similarly alleged that the defendants' statements were misleading because they failed to disclose the FDA's concerns about the company's drug trial. *Homyk*, 2023 WL 3579440, at *8. For example, the defendant in *Homyk* stated "All of our interactions with the agency so far . . . [have] to my mind been straightforward and expected," and "[T]he review process in our opinion is going in a very straightforward, routine manner . . . So, nothing extraordinary to report at this point." *Id*. at *15 (emphasis omitted). The Court found that the plaintiff adequately pled that the challenged omissions were misleading, because any of the risks identified by the FDA that the drug would not be approved "could be important to a reasonable investor." *Id*. The Court also found the plaintiff's theory of motive plausible even if the defendants "truly believed" they could successfully convince the FDA that the omitted adverse facts should not affect the drug's approval. *Id*. at *20.

Here, unlike in *Schueneman*, Klaerner did not "represent that there was no controversy [with the FDA] because all the data was favorable." *Schueneman*, 840 F.3d at 709. And unlike in *Homyk*, as discussed above, the SAC notes multiple instances in which Klaerner directly and specifically described risk factors based on what the FDA might ultimately decide. *See, e.g.*, SAC at ¶¶ 103, 108. Klaerner's failure to disclose all of the specific details of the FDA's concerns does not render all of his opinions conveying optimism about the approval process false and misleading. "That such a dialogue [with the FDA] was ongoing did not prevent [Klaerner] from expressing optimism, even exceptional optimism, about the likelihood of drug approval." *Sanofi*, 816 F.3d at 211.

Therefore, the Court grants Klaerner's motion as to these statements.

2. Factual Statements Alleged to be False or Misleading

(a) Statement that the Advisory Committee Meeting Was Canceled "In Part" Due to COVID-19

The Court previously found that Fiore failed to sufficiently plead that Klaerner's statement

on the May 7, 2020 earnings call that an upcoming Advisory Committee meeting, also known as "AdCom," was canceled "due in part to the logistical challenges posed by COVID-19" was false or misleading. *See* Order at *12; *see also* SAC at ¶¶ 25–26, 158–59. The Court explained that the previous complaint contained no facts "supporting the suggestion that the FDA told Defendants it canceled the AdCom meeting because of problems with the NDA." Order at *12.

In the SAC, Fiore now directly alleges that "[t]he FDA did not cite logistical challenges stemming from COVID-19 as even a contributing factor in canceling the AdCom meeting in its communications with Tricida." SAC at ¶ 159. Instead, citing the documents produced by the FDA, he alleges that the AdCom meeting was canceled because of "the FDA's concerns that there were too many problems with the NDA to even warrant convening an Advisory Committee." *Id.* Specifically, Fiore cites documents detailing communications from the FDA to Tricida beginning in January 2020 in which the Agency identified "significant issues" with the trial and their impact on a potential AdCom meeting, and contends that these issues ultimately led to cancellation of that meeting. *See, e.g.*, *id.* at ¶¶ 72–77, 159. The SAC further alleges that Klaerner knew about these issues because he attended meetings in January and May 2020 at which the FDA discussed them. *Id.* at ¶¶ 163–65.

Klaerner argues that "[s]aying that the need for a meeting is 'no longer obvious' is a far cry from saying that the meeting will not take place and even further removed from a statement that the drug will not be approved," and contends that the minutes of the mid-cycle meeting cited by Fiore show that the AdCom meeting was still on the table. Mot. at 17. However, construing the pleadings in the light most favorable to Fiore, the Court concludes that he has sufficiently alleged that Klaerner's May 7 statement was false or misleading given that the FDA never cited COVID-19 logistics as the reason for the cancellation. *Cf. Sanofi*, 816 F.3d at 214 (finding the plaintiffs' claims failed in the absence of plausible allegations showing a "direct conflict" between the defendants' statements and the FDA feedback). Fiore plausibly pleads that Klaerner misled investors as to the true reasons, even "in part," for why the AdCom meeting was canceled, "affirmatively creat[ing] an impression of a state of affairs that differ[ed] in a material way from the one that actually exist[ed]." *Brody*, 280 F.3d at 1006 (citation omitted). Thus, "there is a

substantial likelihood that the disclosure of the [allegedly] omitted fact"—namely, that the FDA referenced its concerns with the NDA, and never referenced the COVID-19 pandemic, in canceling the AdCom meeting—"would have been viewed by the reasonable investor as having significantly altered the total mix of information available." *Irving*, 398 F. Supp. 3d at 556.

Therefore, the Court denies Klaerner's motion to dismiss on this ground.

(b) Other Alleged Omissions

Similarly, the SAC identifies other factual representations that Fiore contends were misleading with respect to Tricida's likelihood of achieving FDA approval. For example, Klaerner stated that "[o]ne hundred ninety-six of the 208 subjects who completed the 12-week treatment period in our pivotal Phase 3 trial, TRCA-301, agreed and were eligible to continue in our extension trial, TRCA-301E, which we completed in March 2019." SAC at ¶ 125. Fiore argues that this statement was misleading because very few patients in the United States continued on and completed the full 52-week trial, and the FDA had warned Tricida not to rely on a patient population outside of the United States. *Id*. at ¶¶ 127, 138.

The Court finds that the SAC does not adequately plead that these omissions identified by Fiore made the affirmative factual statements false or misleading. Importantly, Tricida did disclose to investors that the majority of the trial participants were outside of the United States and explained how that fact could affect FDA approval. *Id*. at ¶ 103 ("We conducted the TRCA-301 trial and are conducting the TRCA-301E trial with majority enrollment outside the United States and may, in the future, conduct clinical trials of our product candidates outside the United States. The FDA may not accept such foreign clinical data . . . .") (emphasis omitted). Viewing the identified statements in context, *Omnicare*, 575 U.S. at 190, Fiore does not explain how Klaerner's omissions affected the "total mix" of information available to a reasonable investor, *Irving*, 398 F. Supp. 3d at 556, or why the disclosures Klaerner did make gave reasonable investors a misleading impression of the actual state of affairs, *Berson v. Applied Signal Tech., Inc.*, 527 F.3d 982, 987 (9th Cir. 2008), given that there is no "freestanding completeness requirement" under the securities laws, *Brody*, 280 F.3d at 1006.

Accordingly, the Court grants Klaerner's motion as to these factual statements.

B. Scienter

a. Legal Standard for Scienter

Klaerner also contends that Fiore's allegations are insufficient to support a "strong inference" of scienter. Mot. at 22–30. Under the PSLRA, whenever intent is an element of a claim, the complaint must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2)(A). "The PSLRA's strong inference requirement has teeth," and "is an exacting pleading obligation" that "present[s] no small hurdle for the securities fraud plaintiff." *Nguyen v. Endologix, Inc.*, 962 F.3d 405, 414 (9th Cir. 2020) (citing *Zucco Partners*, 552 F.3d at 990). "A complaint will only survive only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any plausible opposing inference one could draw from the facts alleged." *Tellabs, Inc. v. Makor Issues & Rts., Ltd.*, 551 U.S. 308, 310 (2007). "In this circuit, the required state of mind is a mental state that not only covers intent to deceive, manipulate, or defraud, but also deliberate recklessness." *E. Ohman J:or Fonder AB v. NVIDIA Corp.*, 81 F.4th 918, 937 (9th Cir. 2023) (citation omitted). "'[D]eliberate recklessness' is more than '*mere* recklessness or a motive to commit fraud.'" *Nguyen*, 962 F.3d at 414 (citations omitted) (emphasis in original). "It is instead 'an *extreme* departure from the standards of ordinary care,' which 'presents a danger of misleading buyers or sellers that is either known to the defendant or is so *obvious* that the actor must have been aware of it.'" *Id*. (citation omitted) (emphasis in original).

As in its prior order, the Court addresses scienter as to the statements it previously found were adequately alleged to have been material misrepresentations and omissions, as well as the one new misrepresentation it finds to be sufficiently pled.[6]

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[6] Fiore sets forth no new arguments regarding scienter as to the theories rejected by the Court in its last order. *See* Order at *14–15 (discussing Fiore's allegations that Defendants were motivated to mislead the market because they otherwise would have run out of money, and that Klaerner made suspicious stock sales, as well as Fiore's generalized claims under the "core operations" theory). Accordingly, the Court does not revisit its prior rulings on these bases, other than to again consider whether the totality of the current allegations adequately plead scienter when viewed holistically.

b. Statements About the Location of the Phase 3 TRCA-301/TRCA-301E Trial Sites

The Court previously found that Fiore did not plausibly allege scienter with respect to the statements that Tricida conducted its Phase 3 trials in "Europe." *See* Order at *15–16. The Court reasoned that "there [were] no allegations supporting the required 'strong inference' that Defendants intended to mislead or were deliberately reckless in characterizing the trial location as 'Europe' generally." *Id*. at *16. "Put another way, as alleged, nothing about the claimed underlying representativeness problems meets this high 'so obvious' standard, such that Defendants would have known that their literally true use of 'Europe' would be misleading." *Id*.

Fiore now contends that the new FDA documents supply what was missing in the prior complaint. Specifically, the SAC provides additional allegations derived from the FDA documents indicating that Klaerner attended meetings at which the FDA specifically cautioned Tricida against relying on patient data from Eastern European countries. *See, e.g*., SAC at ¶¶ 57–58, 69, 76, 98, 140, 188; *see also* Opp. at 12. Klaerner argues that these allegations are no different than those previously rejected by the Court, in that they amount to the assertion that Defendants knew "the FDA would be less likely to accept their NDA because it relied on clinical trial data from Eastern European patients who are unlikely to be representative of the U.S. patient population and U.S. medical care." Order at *16.

The Court agrees with Klaerner and finds that Fiore's allegations again fail to raise a "strong inference" of scienter. As the Court found in its prior order, there are no allegations in the SAC plausibly pleading that the literally true characterization of the trial location as "Europe" generally amounted to "an extreme departure from the standards of ordinary care, and which present[ed] a danger of misleading buyers or sellers" that was either known to Klaerner or so obvious that Klaerner must have been aware of it. *Zucco Partners*, 552 F.3d at 991; *see also* Order at *16.

Klaerner also convincingly argues that the fact that Tricida specifically directed the market to information disclosing the location of the trials cuts against any inference of scienter. *See* Mot. at 26. For example, Tricida conveyed this information through articles published by *The Lancet*, and Klaerner later highlighted the *Lancet* publication on an earnings call. *See* Dkt. No. 128-17

(Ex. 15) at 7 ("I would like to highlight the publication of our Phase III TRC101 clinical trial results in The Lancet, a leading independent general medical journal."). Such actions further negate any inference of scienter. *See, e.g.*, *Rigel*, 697 F.3d at 885 ("if the individual defendants were acting based on their belief that they had a financial motive to conceal the 'true' results of the clinical trial, they would not have voluntarily publicly disclosed all the data and the statistical methodology."); *Nguyen*, 962 F.3d at 417 (finding the plaintiff was "hard-pressed to build a fraud case" around a study when she admitted in her complaint that the defendant "acknowledged and discussed this very study on an investor conference call").

Accordingly, the Court again finds that Fiore fails to sufficiently allege scienter as to these statements.

c. Risk Disclosures About the Location of the Phase 3 TRCA-301/TRCA-301E Trial Sites

Similarly, in its prior order, the Court concluded that Fiore did not plausibly allege scienter as to the risk disclosures regarding Tricida's use of foreign clinical data. *See* Order at *15. The Court explained that the scienter analysis for these disclosures tracked that for the "Europe" statements "because both flow from the same contention that Defendants knew the FDA would be less inclined to accept their NDA because it relied on clinical trial data taken from Eastern European patients unlikely to be representative of the U.S. patient population and U.S. medical care." *Id*. The only difference between the risk disclosures and the "Europe" characterization was that Fiore alleged Defendants misrepresented the risk that the FDA would deny Tricida's NDA because of deficiencies in the clinical trial data. *Id*.

For the same reasons outlined above, the Court again finds that there are no allegations in the SAC plausibly pleading that the risk disclosures meet the high "so obvious" standard such that Klaerner would have to know that Tricida's disclosures would be misleading. *See* Order at *16. Namely, Fiore's allegations based on Klaerner's participation in the FDA approval process are insufficient to substantiate a plausible "strong inference" that Klaerner intended to mislead or was deliberately reckless in disclosing a generalized risk that the FDA *could* reject foreign clinical data submitted in the NDA. *See* Order at *16. And as discussed above, the SAC acknowledges

Klaerner's statement communicating the risks associated with Tricida's reliance on foreign clinical data. *See, e.g.*, SAC at ¶ 103 ("We conducted the TRCA-301 trial and are conducting the TRCA-301E trial with majority enrollment outside the United States and may, in the future, conduct clinical trials of our product candidates outside the United States. The FDA may not accept such foreign clinical data . . . .") (emphasis omitted).

Therefore, the Court again concludes that Fiore fails to adequately plead scienter as to the risk disclosures.

d. Statements About the Multicenter Nature of the Phase 3 TRCA-301/TRCA-301E Trial[7]

The Court also previously found that Fiore's scienter allegations with respect to statements describing Tricida's Phase 3 trial as "multicenter" were insufficient to survive dismissal. *See* Order at *16–17. The Court found that, "as with the previous statements, there [were] no allegations supporting the 'strong inference' that Defendants intended to mislead or were deliberately reckless in labeling the trial as 'multicenter,' especially given that there does not appear to be any dispute that the trials were in fact 'conducted at 47 sites' as alleged in the complaint." *Id.* at *17 (citing *Zucco Partners*, 552 F.3d at 991).

Here, there still appears to be no dispute that the trials were "conducted at 47 sites." *See, e.g.*, SAC at ¶ 95 ("most trial sites for the TRCA-301/TRCA-301E trial were in Eastern Europe" and "one Bulgarian site in particular was entirely responsible for the long term treatment effects seen in the study"). The SAC otherwise contains no particularized allegations in support of its claim that Defendants "knew or recklessly disregarded the truth" in characterizing the trial as "multicenter," *id.*, and Fiore's assertions about Klaerner's participation in the FDA approval process do not tip the scales. Thus, the allegations in the SAC do not alter the Court's previous finding that it "cannot conclude that the inference that [Klaerner] acted with deliberate recklessness or intent to mislead investors is 'at least as compelling' as the inference that [he] did not." Order at *17 (citing *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 50 (2011)).

[7] In his opposition brief, Fiore now concedes that some of these "multicenter" statements did not mislead investors. *See* Opp. at 15 n.5.

As a result, the Court again finds that Fiore fails to sufficiently allege scienter as to these statements and grants Klaerner's motion on this basis.

e. Statement Related to the Cancellation of the Advisory Committee Meeting

Finally, the Court concludes that Fiore has plausibly alleged scienter with respect to Klaerner's statement that the AdCom meeting was canceled in part due to "the logistical challenges posed by COVID-19." Fiore pleads that on January 24, 2020, well before the start of the COVID-19 pandemic in the United States, the FDA "expressly informed Defendants" that, given "significant issues" it identified with the TRCA-301 and TRCA-301E trials, it was "no longer obvious" to the Agency that the AdCom meeting was needed. SAC at ¶ 159; *see also id*. at ¶¶ 72–74 (detailing two of the "significant issues" identified by the FDA on January 24, 2020, and alleging that "[a]s a result of these 'significant issues[,]' the FDA told Tricida that an advisory-committee meeting was no longer needed"). The FDA allegedly reiterated these issues on several occasions. For example, on April 17, 2020, the FDA sent Tricida a package ahead of the upcoming late-cycle meeting, the purpose of which was to discuss any outstanding review issues, and stated that it "remain[ed] concerned about the magnitude and durability of the treatment effect." *Id*. at ¶ 75. The same package reminded Tricida that, at an earlier meeting, the FDA had "indicated that it was not clear that the results of TRCA-301/301E were applicable to the U.S. population and practice of medicine," and that Tricida's decision to enroll participants at sites in Eastern Europe was "particularly problematic" due to the prevalence of patients affected by BEN in that region. *Id*. at ¶¶ 76–77; *see, e.g., id*. at ¶ 76 ("We are concerned that the response to treatment in patients with BEN (i.e., the size of the treatment effect on blood bicarbonate) may not be representative of the size of the treatment effect in patients in the U.S. with metabolic acidosis associated with CKD who do not have BEN.") (emphasis omitted). Then, at the late-cycle meeting on May 1, 2020, the FDA repeated the substantive review issues it had laid out in the April 17, 2020 package, and told Tricida once again that it did not believe an AdCom meeting was needed. *Id*. at ¶ 77.

Six days later, after stating that the AdCom meeting would be canceled in part due to

COVID-19 "logistical issues," Klaerner shared only one of the outstanding review issues raised by the FDA at the late-cycle meeting—"the magnitude and durability of the treatment effect on the surrogate markup." *Id*. at ¶ 158. Klaerner then concluded that "[o]verall, while the FDA continues its review, we remain confident that our submission meets the standard for approval through the Accelerated Approval Program." *Id*.

The Court finds that Fiore plausibly pleads that Klaerner intentionally or recklessly misrepresented the true reasons for the cancellation of the AdCom meeting. The SAC alleges that Klaerner was party to extensive communications with the FDA about its concerns and their potential impact on the AdCom meeting, and that the FDA did not at any point cite COVID-19 logistical issues as the reason for canceling the meeting. SAC at ¶¶ 159, 162. And the SAC pleads that Klaerner selectively raised only one of the FDA's concerns in the May 7, 2020 call, but not others, thereby misleading the market by omission. *Id*. at ¶ 158. Under the circumstances, it was obviously relevant whether the meeting was canceled for "logistical reasons" or substantive ones, and it was also relevant what the full substantive reasons were once Klaerner chose to highlight some of them. *See Schueneman*, 840 F.3d at 709. It is plausible that a seasoned pharmaceutical executive like Klaerner would be aware that the FDA's reasons for canceling a critical meeting would be highly significant to investors. These allegations thus plausibly plead "an extreme departure from the standards of ordinary care, and which presents a danger of misleading buyers or sellers" that was either known to Klaerner or so obvious that he must have been aware of it. *Zucco Partners*, 552 F.3d at 991.

Therefore, the Court denies Klaerner's motion on this ground.

V. CONCLUSION

For the reasons stated above, the Court rules as follows:

1. The Court **DENIES** Klaerner's motion to dismiss as to Fiore's claim based on canceling the Advisory Committee meeting in part due to COVID-19.[8]

[8] As with its prior order, because the Court finds that at least one Section 10(b) claim has been adequately pled, and because neither party substantively addressed the Section 20(a) control person claim other than to note that it depends on a showing of a primary Section 10(b) violation, the Court also **DENIES** the motion to dismiss that claim.

2. The Court **GRANTS** Klaerner's motion to dismiss as to Fiore's other claims **WITHOUT LEAVE TO AMEND** due to the failure to adequately plead falsity and scienter. *See Zucco Partners*, 552 F.3d at 1007 ("where the plaintiff has previously been granted leave to amend and has subsequently failed to add the requisite particularity to its claims, '[t]he district court's discretion to deny leave to amend is particularly broad.'") (citation omitted).

In sum, at this stage of the proceedings, the Court has found that two categories of statements about the May 1, 2020 late-cycle meeting are actionable under the PSLRA and may proceed: (1) the statements discussing outstanding review issues with the FDA that the Court found in its prior order found to be sufficiently pled, *see* Order at *12–14, 17–18; and (2) the statement that the AdCom meeting was canceled "due in part to the logistical challenges posed by COVID-19" that the Court now finds is sufficiently pled.

The Court further **SETS** a telephonic case management conference for March 26, 2024 at 2:00 p.m. The Court further **DIRECTS** the parties to submit a joint case management statement by March 19, 2024. All counsel shall use the following dial-in information to access the call:

Dial-in: 888-808-6929

Passcode: 6064255

For call clarity, parties shall NOT use speaker phone or earpieces for these calls, and where at all possible, parties shall use landlines. All attorneys appearing for a telephonic case management conference are required to dial in at least 15 minutes before the hearing to check in with the CRD.

IT IS SO ORDERED.

Dated: 3/11/2024

HAYWOOD S. GILLIAM, JR.
United States District Judge

United States District Court
Northern District of California